Bryon J. Benevento (5254)
Kimberly Neville (9067)
Snell & Wilmer L.L.P.
15 West South Temple, Suite 1200
Gateway Tower West
Salt Lake City, UT 84101
Telephone: (801) 257-1900
Facsimile: (801) 257-1800

Perry J. Viscounty (132143), *Pro Hac Vice*
Mark A. Finkelstein (173851), *Pro Hac Vice*
Latham & Watkins LLP
650 Town Center Drive, 20th Floor
Costa Mesa, CA 92626
Telephone: (714) 540-1235
Facsimile: (714) 755-8290

Attorneys for Defendant and Counterclaimant
Allergan, Inc.

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, CENTRAL DIVISION

KLEIN-BECKER usa, LLC, a Utah limited liability company,

Plaintiff,

v.

ALLERGAN, INC., a Delaware corporation, and MEDIACOM WORLDWIDE, INC., a Delaware corporation,

Defendants.

ALLERGAN, INC., a Delaware corporation,

Counterclaimant,

v.

KLEIN-BECKER usa, LLC, a Utah limited liability company,

Counter-Defendant.

MEMORANDUM IN SUPPORT OF DEFENDANT ALLERGAN, INC.'S MOTION TO DISMISS FIRST, SECOND, AND THIRD CLAIMS IN KLEIN-BECKER USA, LLC'S SECOND AMENDED COMPLAINT

CASE NO.: 2:03CV00514 DB
Honorable Dee Benson

Magistrate Brooke C. Wells

(Oral Argument Requested)

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Defendant and counterclaimant Allergan, Inc. ("Allergan") hereby submits this memorandum in support of its Motion to Dismiss the First, Second, and Third Claims in plaintiff and counterdefendant Klein-Becker usa, LLC's ("Klein-Becker") Second Amended Complaint ("SAC").

I. INTRODUCTION

After adopting a worldwide advertising campaign to promote its unproven and unapproved wrinkle cream StriVectin-SD as "Better than Botox®?," using false statements and unlawful comparisons to Allergan's FDA-approved BOTOX® and BOTOX® Cosmetic products, Klein-Becker now attempts an offensive strike that would mutate this lawsuit in a manner not permitted by federal and Utah state law. Klein-Becker's attempt to shift attention away from its own unlawful conduct cannot succeed because each of the three claims it attempts to add fails to state a claim on which relief can be granted.

In its new First Cause of Action, Klein-Becker seeks to cancel Allergan's registered trademarks based on an incorrect interpretation of the Lanham Act's "use in commerce" requirement. Even accepting Klein-Becker's allegations as true for purposes of this motion, Klein-Becker alleges only that Allergan did not make commercial sales of BOTOX® Cosmetic prior to filing the applications for its BOTOX® marks. Making commercial sales is only one basis for "use in commerce" under the Lanham Act: the other is transportation of goods bearing the mark. Specifically, a shipment of a pharmaceutical product for purposes of clinical trials constitutes "use" within the meaning of the Lanham Act. Klein-Becker does not, and cannot, allege that Allergan did not make such use of its marks and thereby establish trademark ownership for purposes of registering BOTOX®, prior to the date of first use stated in

its trademark applications. For this reason, Klein-Becker's claim for cancellation must be dismissed.

By its Second Cause of Action, Klein-Becker, who is the party engaging in blatantly false comparative advertising by unlawfully using Allergan's federally registered trademarks, seeks to bring claims against Allergan for Lanham Act false advertising and common-law unfair competition for Allergan's use of the FDA-approved name for Allergan's own product. Under settled law, Klein-Becker's claims are preempted by the federal Food, Drug & Cosmetics Act ("FDCA") and the regulations promulgated under the FDCA. The FDCA grants exclusive jurisdiction to the U.S. Food & Drug Administration ("FDA") to regulate the sale and marketing of drugs in the United States. A Lanham Act or unfair competition claim, such as Klein-Becker's, that asks the Court to adjudicate branding claims made by drug manufacturers invades the FDA's exclusive jurisdiction under the FDCA and therefore must be dismissed. All other bases for Klein-Becker's Lanham Act claim have previously been dismissed from the First Amended Complaint ("FAC") and should likewise be dismissed here.

Finally, Klein-Becker's renewed claim for unfair competition under Utah common law fails because Klein-Becker, in its SAC as in its FAC, pleads no facts to suggest that Allergan attempted to pass off its own goods as those of Klein-Becker's, or seized for its own benefit something of value that Klein-Becker had built up. As this Court has already held in this case, passing off or palming off and misappropriation are the *only* two bases for Utah common-law unfair competition, and "this Court is not inclined to expand Utah common law to address

some other type of conduct."[1] Klein-Becker's attempt to add back into its complaint a claim this Court has already dismissed is an abuse of process that should, yet again, be rejected.

II. BACKGROUND FACTS AND PROCEDURAL HISTORY

1. Allergan is a global specialty pharmaceutical company that develops and commercializes innovative products for the eye-care, neuromodulator, skin-care, and other specialty markets. One of its many products is BOTOX®, which the FDA has approved for several uses. Klein-Becker's Second Amended Complaint ("SAC") ¶¶ 10, 14. BOTOX® has been approved by the FDA for, among other things, blepharospasms, a localized movement disorder that affects the muscles that control eyelid movement and can lead to blindness; strabismus (also known as crossed eyes), a disorder in which the eyes are misaligned; and cervical dystonia, a disorder characterized by involuntary tonic contractions or intermittent spasms of the neck muscles. *Id.* ¶ 14. BOTOX® Cosmetic is FDA-approved, and used for cosmetic applications, specifically as a prescription product to reduce the appearance of glabellar lines, which are vertical lines between the eyebrows. *Id.* ¶ 19.

2. Klein-Becker markets and sells purported weight-control and life-enhancement products including StriVectin-SD, an untested cream originally marketed to reduce the appearance of stretch marks and now touted as an anti-wrinkle product. SAC ¶¶ 7-9. Klein-Becker adopted a marketing campaign for StriVectin-SD that attempts unfairly to trade off of the superior goodwill that Allergan has generated with its BOTOX® Cosmetic product. *See id.* ¶¶ 40-42.

[1] Order on Defendant Allergan, Inc.'s Motion to Dismiss Plaintiff's First Amended Complaint (signed Nov. 19, 2003) ("Nov. 19, 2003 Order").

3. When it became aware of Klein-Becker's false and misleading ads, Allergan attempted to resolve the issue by sending a letter to Klein-Becker requesting that it cease its use of the false and misleading "Better than Botox" advertisements. SAC ¶ 43, Ex. D. Although Allergan's letter did not create a judiciable case or controversy that would merit legal relief, in a tactical move Klein-Becker immediately filed a declaratory relief action with this Court before even responding to Allergan's letter. Klein-Becker later amended its complaint to bring affirmative claims against both Allergan and its media buying and planning agency, MediaCom Worldwide, Inc. ("MediaCom"). Although MediaCom was named as a defendant in Klein-Becker's initial and First Amended Complaint ("FAC"), Klein-Becker has not named MediaCom as a defendant in the SAC.

4. On July 30, 2003, Allergan filed a motion to dismiss Klein-Becker's First Amended Complaint. Allergan moved for dismissal of, among other claims, Klein-Becker's claim for Lanham Act unfair competition because Klein-Becker's allegations demonstrated on their face that Allergan did not make any false or misleading representation of fact in commercial advertising or promotion. Defendant Allergan, Inc.'s Motion to Dismiss Plaintiff's First Amended Complaint (filed July 30, 2003) at 4-6. Allergan also moved to dismiss Klein-Becker's claim for common-law unfair competition because Klein-Becker pleaded no facts to suggest that Allergan attempted to pass off its own goods as those of Klein-Becker or seized for its own benefit something of value that Klein-Becker had built up. *Id.* at 6-7.

5. By order dated November 19, 2003, this Court granted Allergan's motion to dismiss in part, finding that Klein-Becker had not alleged facts to supports its unfair competition claim under the Lanham Act or its unfair competition claim under Utah common

law. Nov. 19, 2003 Order at 2; *see* SAC at 16 n.2; *id.* at 18 n.3. In dismissing the common-law claim, the Court stated that it "is not inclined to expand Utah common law to address some other type of conduct," other than passing off or palming off or misappropriation. Nov. 19, 2003 Order at 2.

6. In support of its new claim to cancel Allergan's marks, Klein-Becker alleges that Allergan applied for a trademark registration for BOTOX® on January 3, 2001, and represented in its applications that Allergan had used the mark for "pharmaceutical preparations for the treatment of . . . wrinkles" since 1990, with use in commerce since 1992. SAC ¶ 15, Ex. A. While Klein-Becker alleges that Allergan did not sell BOTOX® for the treatment of wrinkles in 1990 or 1992 because FDA had not yet approved BOTOX® for the treatment of lines on the face (*id.* ¶¶ 16, 18), Klein-Becker does not allege that Allergan did not ship its pharmaceutical product for purposes of scientific trials at that time.

7. According to the FDA's records, published studies of BOTOX® for the treatment of wrinkles date back to 1992. Allergan, Inc.'s Request for Judicial Notice, filed concurrently herewith ("RJN"), Ex. A (Carruthers JD, Carruthers JA: *Treatment of glabellar frown lines with C. botulinum-A exotoxin*, J Dermatol. Surg. Oncol. 18:17 (1992)). Clinical studies focused on the efficacy of BOTOX® for treatment of wrinkles began at least as early as 1999. *Id.* Ex. B (FDA Medical Officer's Review (submitted Dec. 2000)). After a lengthy pre-approval and approval process that spanned multiple years, BOTOX® Cosmetic was approved by the FDA in 2002 for the treatment of a particular kind of facial wrinkles: glabellar lines between the brow. SAC ¶¶ 19, 30.

8. In support of its renewed claim for Lanham Act false advertising, Klein-Becker alleges that FDA regulations—that is, the FDCA, which provides no private right of action—prohibit Allergan from marketing or promoting BOTOX® Cosmetic for off-label uses or for "wrinkles" in general. SAC ¶¶ 21-22. Klein-Becker alleges that in violation of the FDA's rules and regulations, Allergan nevertheless trains and sponsors physicians to use BOTOX® Cosmetic for off-label uses. *Id.* ¶ 23-24. Admitting that the FDA itself authorized "BOTOX® Cosmetic" as the name of Allergan's product, Klein-Becker alleges that by using this FDA-approved brand name, Allergan is "mischaracterizing" and "unlawfully promoting" its product. *Id.* ¶¶ 25-29.

9. Klein-Becker does not attach a single BOTOX® Cosmetic advertisement to its SAC. Instead, further attempting to state a private cause of action under a federal regulatory scheme that does not provide for one, Klein-Becker attaches two letters sent by FDA to Allergan in September 2002 and June 2003 as part of FDA's enforcement activities under the FDCA. *Id.* ¶¶ 33-35, Exs. B, C. These letters do not represent any final ruling or finding by the FDA, nor do they provide evidence that Allergan is or ever was using an advertisement that contained a false or misleading statement of fact. Klein-Becker's attempt to enforce the FDCA—when enforcement authority rests exclusively with the federal government—is particularly disingenuous while Klein-Becker is itself attempting to evade FTC and FDA enforcement action for its own patently false advertising (*see* RJN Exs. C, D, E). Klein-Becker's Lanham Act and common-law unfair competition claims seek to enforce against Allergan a claim for marketing a drug in violation of the FDCA and FDA's regulations promulgated thereunder, in direct violation of the FDCA's exclusive jurisdiction provisions.

10. Klein-Becker does not allege that BOTOX® Cosmetic is not a "cosmetic" under the ordinary, lay-person definition of the word. Instead, Klein-Becker alleges only that the FDA, despite specifically authorizing the name of the product, has not approved BOTOX® Cosmetic as a cosmetic. SAC ¶ 30.

11. Unlike BOTOX® and BOTOX® Cosmetic, Klein-Becker does not allege that StriVectin-SD has been proven by any clinical studies, let alone the months and years of extensive clinical trials necessary to apply for and obtain FDA approval. Achieving FDA approval is a lengthy, expensive, demanding process that the FDA imposes "in order to protect the welfare of the public at large." *Id.* ¶ 22. Allergan's BOTOX® Cosmetic has successfully attained this distinguished goal; Klein-Becker's StriVectin-SD product has not. Nevertheless, Klein-Becker makes the illogical allegation that by using the FDA-approved name of its own product, Allergan is "improperly attempting to compete with Klein-Becker in the cosmetic skin-care market . . . ." *Id.* ¶ 37. And, despite making the overt judicial admission that "comparing Botox Cosmetic and StriVectin-SD is improper" (*id.* ¶ 38), Klein-Becker continues to market StriVectin-SD almost exclusively with the false comparative slogan "Better than Botox®?"

III. ARGUMENT

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court may dismiss a claim as a matter of law when it is clear that the plaintiff cannot prove any set of facts upon which relief can be granted. *TV Communications Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1024 (10th Cir. 1992). Klein-Becker's claims for cancellation of Allergan's trademarks, Lanham Act false advertising, and common-law unfair competition must be dismissed under Rule 12(b)(6) because Klein-Becker cannot prove any set of facts upon which relief can be granted as to any of these claims.

A. Klein-Becker's Claim For Cancellation Of Allergan's Registered Trademarks Fails Because Klein-Becker Does Not, And Cannot, Allege That Allergan Committed Fraud On The Trademark Office Or Otherwise Committed Any Act Supporting Cancellation Of Its Marks.

Klein-Becker alleges two grounds for cancellation of Allergan's marks: fraud in the procurement of the trademark registrations, and unlawful use of the trademark in violation of FDA regulations and the Lanham Act. SAC ¶ 63. Both grounds are legally unsupportable.

1. Klein-Becker Alleges Only That Allergan Did Not Sell Goods Bearing The Mark, Not That Allergan Did Not Transport Goods Bearing The Mark, Prior To 1992. Either Sales Or Transportation Is Sufficient For "Use In Commerce" Under The Lanham Act.

To allege a claim for cancellation of Allergan's trademarks based on fraud in procuring the marks, Klein-Becker would have to plead with specificity "(1) the false representation regarding a material fact; (2) the registrant's knowledge or belief that the representation is false (scienter); (3) the intention to induce action or refraining from action in reliance on the misrepresentation; (4) reasonable reliance on the misrepresentation; and (5) damages proximately resulting from such reliance." *United Phosphorus, Ltd. v. Midland*

Fumigant, Inc., 205 F.3d 1219, 1226 (10th Cir. 2000); 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 31:61, p. 31-117 (4th ed. 2004). Like any claim for fraud, a complaint for fraud in the procurement of a trademark must "state with sufficient specificity the factual bases for [the] allegation." *San Juan Prods., Inc. v. San Juan Pools, Inc.*, 849 F.2d 468, 472 (10th Cir. 1988) (internal quotation omitted). "Rule 9(b) requires that the pleadings contain explicit rather than implied expression of the circumstances constituting fraud." *Id.*; *see* Fed. R. Civ. P. 9(b). Klein-Becker has failed to plead at all, let alone with specificity, either that Allergan made a false representation of fact, or that the alleged misrepresentation of fact was material.

First, Klein-Becker fails to plead that Allergan made a false representation of fact in its trademark applications. Klein-Becker alleges only that Allergan represented to the U.S. Patent & Trademark Office ("PTO") that Allergan had used the BOTOX® marks "for pharmaceutical preparations for the treatment of . . . wrinkles" by 1990, and had used the mark for the same goods "in commerce" by 1992. SAC ¶¶ 15-18, Ex. A. Klein-Becker alleges that this representation was false because in 1992 the FDA had not yet approved BOTOX® for the treatment of wrinkles and, thus, Allergan had not sold goods bearing that mark by that time. *Id.*

Klein-Becker's argument fails as a matter of law because the "use in commerce" requirement (*see generally* 15 U.S.C. § 1051) is satisfied when a mark is affixed to the goods with which it is associated and those goods are then "sold *or* transported in commerce." *Id.* § 1127 (emphasis added). Accordingly, "use in commerce" in order to establish trademark ownership does not require, as Klein-Becker alleges, that an applicant "market, sell or advertise" goods bearing the mark. SAC ¶ 16. Instead, absent actual commercial sales of goods,

transportation alone is sufficient to establish trademark ownership. *Gen. Healthcare Ltd. v. Qashat*, 364 F.3d 332, 335 (1st Cir. 2004) (*citing New England Duplicating Co. v. Mendes*, 190 F.2d 415, 417 (1st Cir. 1951) ("The use of the disjunctive 'or' between 'sold' and 'transported' leaves no doubt that a transportation . . . is enough to constitute a 'use' even without a sale")); *Planetary Motion, Inc. v. Techsplosion, Inc.*, 261 F.3d 1188, 1196 (11th Cir. 2001) ("[T]he existence of sales or lack thereof does not by itself determine whether a user of a mark has established ownership rights therein."); 3 McCarthy, § 19:118.

Congress has made it clear that a shipment of a pharmaceutical product for purposes of pre-approval scientific trials constitutes "use" within the meaning of the Lanham Act. *See* Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, at 44-45 (Sept. 15, 1988) *reprinted in* 1988 U.S.C.C.A.N. 5577, 5607 ("[T]he definition [of 'use in commerce'] should be interpreted with flexibility so as to encompass various genuine, but less traditional, trademark uses, such as . . . ongoing shipments of a new drug to clinical investigators by a company awaiting FDA approval . . . ."). According to its legislative history, the Lanham Act specifically contemplates that the "use in commerce" requirement will be met long before a drug obtains FDA approval. *See generally*, 3 McCarthy, § 19:110; *G.D. Searle & Co. v. Nutrapharm, Inc.*, No. 98 Civ. 6890 (TPG), 1999 U.S. Dist. LEXIS 16862, *9-10 (S.D.N.Y. Oct. 29, 1999) (finding shipment of plaintiff's pharmaceuticals for clinical testing is sufficient "use in commerce" to show protectable interest in trademark).

Accepting Klein-Becker's allegations as true, then, the only established fact is that BOTOX® Cosmetic was not approved for commercial promotion or sale in connection with pharmaceuticals for the treatment of wrinkles until 2002. No facts exist to suggest that Allergan

did not transport units of pharmaceuticals for the treatment of wrinkles, bearing the BOTOX® mark, in connection with the lengthy preclinical and clinical trial process Allergan undertook for years prior to approval. Indeed, Klein-Becker itself alleges facts suggesting the opposite is true: BOTOX® Cosmetic was FDA approved for the treatment of particular facial wrinkles in 2002 (SAC ¶ 19), thereby necessarily having proceeded through the protracted FDA pre-approval and approval process that spans many years. The FDA's own records, of which this Court may take judicial notice, corroborate that published studies of BOTOX® for the treatment of wrinkles date back to 1992, with clinical studies into the efficacy of BOTOX® for treatment of wrinkles beginning at least as early as 1999. *See, e.g.*, RJN Ex. A (Carruthers JD, Carruthers JA: *Treatment of glabellar frown lines with C. botulinum-A exotoxin*, J Dermatol. Surg. Oncol. 18:17 (1992)); *id.* Ex. B (FDA Medical Officer's Review (submitted Dec. 2000)). Absent facts to suggest that Allergan did not transport any goods bearing the BOTOX® mark in connection with a pharmaceutical for the treatment of wrinkles—which facts are not alleged and, indeed, do not exist—Klein-Becker's claim for cancellation of Allergan's trademark registrations on the basis of fraud on the PTO must be dismissed.

Second, even if Klein-Becker had alleged that Allergan had neither sold nor transported goods under the mark by 1992—which it has not done and cannot do—Klein-Becker would still have failed to allege that Allergan's representation of first use was material, such that the marks should be cancelled. *See United Phosphorus*, 205 F.3d at 1226 (holding that to allege fraud in procurement of trademark, plaintiff must allege that the misrepresentation was of a material fact). Materiality, in the context of a cancellation proceeding, means that "but for the

misrepresentation, the federal registration either would not or should not have issued." 5 McCarthy, § 31:67 at 31-123.

In a use-based trademark application such as Allergan's,[2] a first-use date, even if false, is not material as a matter of law. *See Colt Indus. Operating Corp. v. Olivetti Controllo Numerico S.p.A*, 221 U.S.P.Q. 73, 76 (T.T.A.B. 1983). The only material representation concerning use dates in a trademark application is the applicant's representation that the mark is used as of the date the application is filed. *Id.* (holding the "only fraud that could be perpetrated on the Office with respect to false dates of first use in an application would be where no use was made as of the filing date of the application"); *Western Worldwide Enterprises Group, Inc. v. Qinqdao Brewery*, 17 U.S.P.Q. 2d 1137, 1141 (T.T.A.B. 1990) (noting TTAB has repeatedly held that for use-based applications, erroneous date of first use does not constitute fraud so long as there was use of the mark prior to filing); *Pony Express Courier Corp. v. Pony Express Delivery Service*, 872 F.2d 317, 319 (9th Cir. 1989) (holding claim of date of first use is not material allegation as long as first use in fact preceded application date).

Accordingly, Klein-Becker's focus on the claimed dates of first use—1990 or 1992—does nothing to allege a misrepresentation of material fact. Even if Allergan had not used its mark on the first-use dates set forth in its applications, such erroneous first-use dates would not support cancellation of the marks because all that is required for a use-based application to mature to registration is that the mark was being used on the date the application was filed. Thus, only the representation that the mark is in use, and not the represented first-use date, is

[2] Applications to register marks can be based either on the prior use of the mark in commerce (15 U.S.C. § 1051(a)) or on the applicant's intent to use the mark in commerce (15 U.S.C. § 1051(b)). Here the two applications that matured to Reg. Nos. 2,510,675 and 2,510,673 were based on Allergan's prior use of the BOTOX® mark in commerce.

material to the PTO's registration decision. *Colt*, 221 U.S.P.Q. at 76. Klein-Becker's allegation that but for the claimed first-use dates, Allergan would not have obtained a trademark registration for BOTOX® for the treatment of wrinkles (SAC ¶ 20) is contrary to law.

Without question, Allergan used the BOTOX® mark in connection with pharmaceutical preparation for the treatment of wrinkles prior to the filing date of Allergan's trademark applications, January 3, 2001. *See, e.g.*, RJN Ex. B (FDA Medical Officer's Review (submitted Dec. 2000); *id.* Ex. A (Carruthers JD, Carruthers JA: *Treatment of glabellar frown lines with C. botulinum-A exotoxin*, J Dermatol. Surg. Oncol. 18:17 (1992)). Even if this Court were to decline to take judicial notice of the FDA's Medical Officer's Review, under Rule 11 Klein-Becker could not assert that the BOTOX® mark was not used prior to January 3, 2001, for wrinkles. Accordingly, as a matter of law, the registrations that resulted from those applications cannot be cancelled for fraud.

2. Unlawful Use Of A Registered Mark Is Not Grounds For Cancellation.

Klein-Becker's allegation that Allergan used its BOTOX® marks in violation of FDA regulations and Section 43(a) of the Lanham Act (SAC ¶ 63) fails to state a basis for cancellation of a trademark registration. A federal trademark registration may be cancelled on only two statutory bases: if the mark never should have registered under 15 U.S.C. § 1052,[3] or if

[3] Section 1052 prohibits registration of a mark that is "immoral, deceptive, or scandalous," "comprises a flag or coat of arms" of a country or State, "comprises a name, portrait, or signature identifying a particular living individual," comprises a mark confusingly similar to a previously used mark, or is merely descriptive. 15 U.S.C. § 1052. Klein-Becker has not alleged that the BOTOX® marks fall within any of these categories.

the mark falls within the enumerated grounds set forth in 15 U.S.C. § 1064.[4] 3 McCarthy, § 20:52. These two statutory provisions together establish that cancellation may be based on only a "ground that would have prevented registration in the first place . . . ." *Cunningham v. Laser Golf Corp.*, 222 F.3d 943, 946 (Fed. Cir. 2000); 3 McCarthy, § 20:21.

Unlawful use of the mark is not one such ground. *See* 15 U.S.C. § 1064; *id.* § 1064. Allegations of unlawful use have no place in requests to cancel a trademark registration. *See Person's Co. v. Christman*, 900 F.2d 1565, 1570-71 (Fed. Cir. 1990). Accordingly, Klein-Becker's allegation of unlawful use as a basis to cancel the mark is without support in the law and should be dismissed.

B. Klein-Becker's Lanham Act False Advertising And Unfair Competition Claims Must Be Dismissed Because They Are Preempted By The Food, Drug & Cosmetic Act And Have Previously Been Dismissed By This Court.

Klein-Becker asserts two purported bases for its false-advertising claim: that Allergan markets its product using the name "BOTOX® Cosmetic" for wrinkles, and that Allergan has interfered with Klein-Becker's ability to advertise StriVectin-SD. SAC ¶¶ 69-70. Both allegations are directly contrary to the law.

1. Klein-Becker's Lanham Act False Advertising And Unfair Competition Claims Based On Allergan's Use Of Its FDA-Approved Brand BOTOX® Cosmetic Are Preempted By The Food, Drug & Cosmetic Act.

Klein-Becker's Lanham Act false advertising and common-law unfair competition claims fail because they impermissibly attempt to redress alleged violations of the

[4] Section 1064 allows cancellation of registrations of marks that have become generic, registrations of marks that are functional or abandoned, registrations that were obtained fraudulently, or registrations of marks being used to "misrepresent the source of the good or services on or in connection with which the mark is used." 15 U.S.C. § 1064(3). Of these bases, Klein-Becker alleges only that Allergan's BOTOX® marks were obtained fraudulently. This allegation fails for the reasons set for in Section III.A.1., *supra*.

FDCA, a function exclusively within the jurisdiction of the FDA. *See* 21 U.S.C. § 301 *et seq.* Klein-Becker alleges that Allergan (i) uses the brand name BOTOX® Cosmetic (SAC ¶¶ 25-31), (ii) trains and sponsors physicians who promote off-label uses (*id.* ¶¶ 23-24, 38), and (iii) markets BOTOX® Cosmetic as a cosmetic for the generalized treatment of wrinkles, all in violation of the scope of its FDA approval. *Id.* ¶¶ 27-37. Each of these allegations necessarily relies on an interpretation of the FDCA.

The FDCA and its promulgated regulations govern the FDA approval process for the marketing of drugs in the United States, the process under which BOTOX® Cosmetic received FDA approval for "the temporary improvement of moderate to severe glabellar lines in patients between the ages of 18 and 65." 21 U.S.C. § 301 *et seq.*; *see* SAC ¶ 19. The FDCA provides that all "proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Klein-Becker's claims improperly attempt to use the Lanham Act and common-law unfair competition to enforce the FDCA.

To decide whether Allergan is "improperly promoting its drug as a cosmetic" for wrinkles (SAC ¶ 27), improperly training or sponsoring doctors to promote off-label uses, or otherwise misbranding its FDA-approved drug, this Court would have to evaluate the indications for which FDA has approved BOTOX® Cosmetic for marketing, what constitutes off-label marketing, and what constitutes misbranding. Each of these inquiries is a "question requiring direct interpretation of FDA rules and regulations" and are thus within the exclusive jurisdiction of the FDA, not the courts. *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 832, 838 (W.D. Tex. 2001) (rejecting plaintiff's Lanham Act claim because the "FDA has primary jurisdiction to decide [plaintiff's] claim that [defendant] has misbranded its product" due to

allegedly incorrect labeling information). Jurisdiction for the regulation of drug marketing is vested "jointly and exhaustively in the FDA and the FTC," not the courts. *Id.* at 833 (holding Lanham Act cannot create cause of action where none exists under FDCA). By attempting to invoke the Lanham Act and common-law unfair competition to hold Allergan's marketing of BOTOX® Cosmetic unlawful, Klein-Becker asks this Court to usurp the exclusive jurisdiction of the FDA.

Courts commonly dismiss Lanham Act and unfair competition claims that seek to invoke an interpretation of the FDA's rules and regulations because such claims are preempted by the FDCA. *See, e.g., Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, *7 (D. Kan. Feb. 26, 1997) (dismissing plaintiff's claim that defendant falsely described its product as "dietary supplement" in violation of the Lanham Act and common law unfair competition because "it is for the FDA and not the court to decide whether defendant's product is properly classified as a 'dietary supplement,' under the FDCA and FDA regulations"); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3rd Cir. 1990) (holding plaintiff was unlikely to prevail on its claim that defendant falsely listed an ingredient in its drug as "inactive," when FDA had not explicitly so found, as "[plaintiff's] position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations"); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 476, 479 (D.N.J. 1998) (dismissing plaintiff's Lanham Act claims that defendant's marketing falsely implied FDA approval for certain uses that were not FDA approved, because such questions "rely on interpretations of the FDCA"); *Summit Tech., Inc. v. High-Line Medical Instr. Co.*, 922 F. Supp. 299, 307, 316 (C.D. Cal. 1996) (dismissing plaintiff's Lanham Act and common-law unfair

competition claims that defendants' ads implied FDA approval that their product did not have, because such claims circumvent the FDCA's denial of a private right of action).

Klein-Becker's complaint attempts to do precisely what these courts reject. According to *Braintree*, "it is for the FDA and not the court to decide whether defendant's product is properly classified as a 'dietary supplement' under the FDCA and FDA regulations." 1997 WL 94237 at *7. In *Sandoz*, "the issue of whether an ingredient is properly labeled 'active' or 'inactive' under FDA standards is not properly decided as an original matter by a district court case." 902 F.2d at 230. In *Summit*, "[f]or this Court to determine whether [defendant] has failed to disclose that he offers the services of a 'custom' device, this Court would be forced to determine whether [defendant] is offering a 'custom' device. Because the FDA has the statutory responsibility for interpreting the FDCA (in the first instance), the Court simply will not tread into this area." *Summit*, 922 F. Supp. at 306. Likewise in this case, it is the FDA's exclusive jurisdiction, and not the courts', to determine whether Allergan properly or improperly markets its product as a "cosmetic" or for "wrinkles" or for off-label uses, or has failed to disclose the scope of its FDA approval. Klein-Becker's attempt to use the Lanham Act and common-law unfair competition to enforce the FDCA is entirely preempted.

In fact, there is even less of a basis for Klein-Becker's false advertising claim than in other cases finding FDCA preemption. As Klein-Becker admits, FDA *has already authorized* the name BOTOX® Cosmetic. SAC ¶ 25. By bringing a Lanham Act claim seeking the opposite ruling under the Lanham Act, Klein-Becker is asking this Court to act directly in contradiction to a previous ruling by the FDA in a realm exclusively entrusted to the FDA's jurisdiction. Permitting Klein-Becker to proceed on a theory that Allergan violated the Lanham

Act simply by placing its FDA-approved drug with its FDA-approved name on the market would, in effect, permit Klein-Becker to use the Lanham Act to usurp the FDA's authority to enforce the FDCA. *Braintree*, 1997 WL 94237 at *4 (citing *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993)). Worse still, if Klein-Becker were to prevail on its Lanham Act claims, Allergan could be subjected to a court order contrary to the FDA's own decision about the name of Allergan's product, creating an irresolvable dilemma for Allergan. *See Braintree*, 1997 WL 94237 at *7. By seeking to bring a false advertising claim for a name the FDA has already weighed in on and approved, Klein-Becker asks this Court to usurp the exclusive enforcement domain of the FDA. In this case even more than most, the Lanham Act and unfair competition claims are preempted and must be dismissed.

Finally, even if Klein-Becker were to allege that BOTOX® Cosmetic is not a cosmetic according to the lay person's understanding of the word—which Klein-Becker has not done and cannot do as a matter of ordinary linguistics[5]—such artful pleading would not circumvent FDCA preemption. The *Braintree* court was appropriately "unwilling to consider evidence establishing an independent lay understanding of the term 'dietary supplement' even though [plaintiff] alleged that [defendant's] labeling of its unapproved product as a 'dietary supplement' was false 'in the ordinary sense . . . .'" Whether BOTOX® Cosmetic is a cosmetic for the treatment of wrinkles under any definition is exclusively within the jurisdiction of the FDA, not the courts.

[5] "Cosmetic" is defined as "serving to beatify the body." Webster's II New College Dictionary (2001). BOTOX® Cosmetic serves to beautify the body and, therefore, is plainly a cosmetic under the ordinary, lay person's definition of cosmetic.

2. Alleged Interference With Klein-Becker's Advertising Cannot Support A False Advertising Claim, As This Court Has Already Held.

The second basis for Klein-Becker's Section 1125(a) false advertising claim—that Allergan interfered with Klein-Becker's advertising and disrupted Klein-Becker's sales by making false representations to companies with whom Klein-Becker advertises (SAC ¶¶ 69-70)—is a repeat of the Section 1125(a) claim in Klein-Becker's FAC, which this Court dismissed. Klein-Becker alleges nothing new to change the result.

In its FAC, Klein-Becker alleged that Allergan improperly interfered with Klein-Becker's advertising and promotion. FAC ¶¶ 34-57, 79-82. In its motion to dismiss the FAC, Allergan argued that Klein-Becker's Lanham Act claim should be dismissed because Klein-Becker's interference allegations failed to allege that Allergan made any false or misleading statement to any person in connection with commercial advertising or promotion, a required element of Section 1125(a). Memorandum in Support of Defendant Allergan, Inc.'s Motion to Dismiss Plaintiff's First Amended Complaint (filed July 30, 2003) at 4-6. By order dated November 19, 2003, this Court dismissed Klein-Becker's Section 1125(a) claim for failure to state a claim. Nov. 19, 2003 Order.

The only new allegation in Klein-Becker's SAC is that Allergan advertises its product by its FDA-approved name BOTOX® Cosmetic and markets it for the treatment of wrinkles and off-label uses. For the reasons set forth in Section III.B.1., *supra*, this allegation is preempted by the FDCA. The only remaining allegation—that Allergan "improperly asserted rights to interfere with and disrupt the sales of cosmetic products" (SAC ¶¶ 70, 46-53)—is simply a repetition of the allegations in the FAC that were dismissed. Even Klein-Becker admits

that the Court previously dismissed its claim but argues, unintelligibly, that because the Court also denied Klein-Becker's motion to dismiss Allergan's false advertising and unfair competition claims for lack of standing, Klein-Becker has the right to repeat its own Section 1125(a) claim. This argument makes no sense. Allergan's claims against Klein-Becker are based on Klein-Becker's use, in commercial advertising and promotion, of false and misleading "Better than Botox®?" ads. The only claims by Klein-Becker that are not preempted by the FDCA allege that Allergan interfered with Klein-Becker's advertisements by making false statements to Klein-Becker's advertising companies. Once again, such activities do not constitute commercial advertising and promotion under the Lanham Act. Once again, Klein-Becker's claim should be dismissed.

C. The Utah Common Law Unfair Competition Claim Must Be Dismissed Because Klein-Becker Cannot Plead Any Actionable Unfair Act.

Finally, Klein-Becker's claim for common law unfair competition must be dismissed because the conduct alleged in the SAC does not fall within the categories of actionable conduct under Utah common law. Indeed, this Court dismissed this exact claim in Klein-Becker's FAC for precisely this reason, and Klein-Becker has failed to include any new allegations that would support a claim for unfair competition under Utah common law. As this Court has already ruled in this action, Utah common-law unfair competition has developed into two branches: (1) passing-off or palming-off claims, and (2) misappropriation claims. Nov. 19, 2003 Order; *see also Proctor & Gamble Co. v. Haugen*, 947 F. Supp. 1551, 1554 (D. Utah 1996). This Court has also granted a motion to dismiss on this exact issue in another case involving an affiliate of Klein-Becker. *See* RJN Ex. F (*Basic Research, LLC v. Cytodyne*

Technologies, Inc., Civil No. 2:99CV-0343PGC, 1/9/03 Order on Motion to Dismiss and to Strike (Cassell, J.) (granting motion to dismiss unfair competition claim on the identical basis)).

A passing-off claim involves a party who engages in a scheme to have its own goods or services "pass" in the marketplace as those of another party. *Proctor & Gamble*, 947 F. Supp. at 1551. A misappropriation claim involves a scheme whereby a party seizes for its own benefit something of value that another party had built up through time, money, or effort, which seizure is then generally used to compete against the aggrieved party. *Id.* Both passing-off and misappropriation claims involve the attempt to profit from the reputation or work of a competitor, and these types of claims are the bounds of common-law unfair competition in Utah. *See Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1279-80 (10th Cir. 2000). The Tenth Circuit is clear that "it is not [its] place to expand Utah state law beyond the bounds set by the Utah Supreme Court." *Id.* at 1280 (quoting *Sellers v. Allstate Ins. Co.*, 82 F.3d 350, 352 (10th Cir. 1996)). This Court reiterated the same position in its November 19, 2003 Order: "this Court is not inclined to expand Utah common law to address some other type of conduct." Nov. 19, 2003 Order at 2.[6]

In its SAC, Klein-Becker does not allege that Allergan engaged in either type of unfair act. The SAC alleges that Allergan made "knowingly false" statements to the PTO in its trademark application for BOTOX®, improperly markets and promotes its BOTOX® Cosmetic as a cosmetic in violation of FDA regulations, and made "implied or express instructions . . .

[6] Here again, Klein-Becker admits that the Court previously dismissed this claim but argues, illogically, that the Court's denial of Klein-Becker's motion to dismiss Allergan's claims somehow permits Klein-Becker to reassert its dismissed Utah common-law claim. SAC at 18 n.3. Allergan's claims have never included a Utah common-law unfair competition claim. This Court's denial of Klein-Becker's motion to dismiss Allergan's Lanham Act claim has no relevance to Klein-Becker's repetition of its previously dismissed common-law unfair competition claim.

and/or threats designed to intimidate [advertisers] to refuse to run the "Better than Botox®?" advertising." SAC ¶¶ 10-53. These allegations, even if true, do not constitute passing-off, palming-off, or misappropriation. Allergan has not attempted to pass off Klein-Becker's products as its own or palm off its products as Klein-Becker's products, or seize for its own benefit anything of value, such as information or goodwill, from Klein-Becker in order to compete against it. Klein-Becker does not even allege as much, nor could it.

To the extent that Klein-Becker attempts to allege generally that Allergan's actions are unfair or wrongful, that Allergan is advertising its drug as a cosmetic, or that Allergan's actions reduced consumers' incentives to select a competing product, "the bounds set by the Utah Supreme Court" do not extend common law unfair competition beyond the two established branches to include any of Allergan's alleged acts. *See Proctor & Gamble*, 222 F.3d at 1280. Klein-Becker's common-law unfair competition claims should, once again, be dismissed.

IV. CONCLUSION

Klein-Becker has again rushed into Court with aggressive claims seeking to shift the focus away from its own wrongdoing. Its claims are meritless. For the foregoing reasons, the first, second, and third claims in Klein-Becker's SAC must be dismissed for failure to state a claim upon which relief can be granted under Fed. R. Civ. Proc. 12(b)(6).

Dated this 7th day of October, 2005.

Bryon J. Benevento
Kimberly Neville
Snell & Wilmer L.L.P.

Perry J. Viscounty
Mark A. Finkelstein
Latham & Watkins LLP

Attorneys for Allergan, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I caused to be served a true and accurate copy of the foregoing **MEMORANDUM IN SUPPORT OF DEFENDANT ALLERGAN, INC.'S MOTION TO DISMISS FIRST, SECOND, AND THIRD CLAIMS IN KLEIN-BECKER USA, LLC'S SECOND AMENDED COMPLAINT**, which was sent via electronic mail and first-class mail, on the 7th day of October, 2005:

James E. Magleby, Esq.
Christine T. Greenwood, Esq.
Jason A. McNeill, Esq.
Magleby & Greenwood, P.C.
170 South Main Street
Suite 350
Salt Lake City, UT 84101

James A. Gale, Esq.
Feldman Gale & Weber, P.A.
201 S. Biscayne Blvd.
Suite 1920
Miami, FL 33131